SEP 1 8 2001

K012899 510(K) SUBMISSION FOR GREEN NITRILE POWDER-FREE MEDICAL EXAMINATION GLOVE
SUBMISSION DATE: 2001-06-15

SUMMARY OF SAFETY AND EFFECTIVENESS

A. INFORMATION

1. SUBMITTER'S

Name:	BEST MANUFACTURING COMPANY
Address:	579 Edison Street Menlo, GA 30731 USA
Telephone Number:	706 862 2302
Contact Person:	David C. Young
Date Summary Prepared:	2001-06-15

2. NAME OF DEVICE

Trade or Proprietary Name:	Nitrile Powder-Free Medical Examination Glove (Green)
Common or Usual Name	Non-Sterile Nitrile Powder-Free Patient Examination Glove
Classification Name:	Patient Examination Glove

3. PREDICATE DEVICE IDENTIFICATION NAME, NUMBER: N-DEX Nitrile Powder-Free Medical Examination Glove, K992170

4. DESCRIPTION OF DEVICE

a. How the device functions:

Nitrile rubber films form an excellent barrier to body fluids and bloodborne pathogens.

b. Scientific concepts that form the basis for the device:

The nitrile rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing fine movement necessary for treatment. The absence of natural rubber latex in the product yields no latex protein allergens.

c. Physical and performance characteristics such as design, materials, and physical properties:

Nitrile rubber is known to create a superior barrier to bloodborne pathogens and body fluids.

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASE OR CONDITIONS THAT THE DEVICE WILL ADDRESS

This is a disposable device, intended for medical purposes, that is worn on the examiner's hand to prevent contamination between the patient and examiner. Powder-free examination gloves are suitable in situations where powder is not desirable.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

- The proposed device is identical to the predicate device, except for the following:

  The proposed device has been rendered green in color, while the predicate is blue.

B. IF SE DECISION BASED ON PERFORMANCE DATA:

1. DISCUSSION OF NON-CLINICAL TESTS

Specification	Proposed N-DEX Nitrile Powder-Free Medical Examination Glove (green)	Predicate N-DEX Nitrile Powder-Free Medical Examination Glove (blue)
Performance Standards	ASTM	ASTM
Watertightness	ASTM	ASTM

2. DISCUSSION OF CLINICAL TESTS

Specification	Proposed	Predicate
Safety		
Rabbit Irritation	Passes	Passes
Guinea Pig Sensitization	Passes	Passes
Modified Draze Test (Human Study)	N/A	Passes

DISCUSSION OF SAFETY OR EFFECTIVENESS DATA OBTAINED
(with specific reference to adverse effects and complications)

See Section M: Biocompatibility Testing.

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE SAFETY AND EFFECTIVENESS, AND Performance =/> PREDICATE PRODUCT

The Nitrile Powder-Free Medical Examination Glove (green) has been carefully compared to a legally marketed device in the 510(k). The data summaries indicate that the proposed product meets or exceeds accepted scores for the predicate product in both physical and nonclinical tests and satisfies the requirements for a safe and effective "powder-free" medical glove.

Pursuant to 21 C.F.R. 807.87 (j), I David C. Young, Director, Regulatory Affairs and Quality Assurance, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Director, Regulatory Affairs and Quality Assurance, for the Best Manufacturing Company, and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material to a review of the substantial equivalence of this device have been knowingly omitted from this submission.

David C. Young, Director, Regulatory Affairs & Quality Assurance

2001-06-15
DATE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2001

Mr. David C. Young
Director of Regulatory Affairs
Best Manufacturing Company
579 Edison Street
Menlo, Georgia 30731

Re: K012899
Trade/Device Name: Green Nitrile Powder-Free Medical Examination Glove
Regulation Number: 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: June 15, 2001
Received: August 29, 2001

Dear Mr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (section 531-542 of the Act; 21); CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: **Best Manufacturing Company**
510(k) Number (if known) K012899 *
Device Name: **Green Nitrile Powder-Free Medical Examination Glove**

The **Green Nitrile Powder-Free Medical Examination Glove** is a disposable device intended for medical purposes; that is worn on the examiner's hand, to prevent contamination between the patient and examiner (21 CFR 880.6250).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter_____
Per 21 CFR 801.109

* For a new submission, do NOT fill in the 510(k) number blank.

Chin S. Lin
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012899